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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,565	10/16/2001	Chin-Chin Tsai	0158/0J927US0	7871
7590 05/26/2004			EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/982,565	Applicant(s) TSAI ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "incompatible" is not clearly described in the specification in that it is unclear what characteristics of the polymer are entailed by this term. Clarification is requested,

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in that they do not particularly point out the metes and bounds of the term "incompatible". Clarification is requested.

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Claims 6-8 are indefinite in the use of the term "synthetic material" since it also does not particularly point out the metes and bounds of this member of the Markush Group. It is suggested that applicant amend the term to read "synthetic polymer(s)".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4-8, 10-12, 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Shastri et al.

Shastri et al disclose a composite polymer matrix which is porous (see Abstract; column 2, lines 28-43.) The voids in the matrix may range from connected, to partially connected, to not connected at all (see col. 1, lines 58-65). Bioactive agents may be

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incorporated into this matrix (see col. 2, lines 39-40). The matrix may further include bioerodible fibers (see col. 2, lines 57-60). Multilayer matrices are specifically recited at col. 25, lines 40 et seq. And a specific suggestion to combine two materials with different properties, and pore sizes is found at col. 26, lines 1-11. This matrix may also contain a bioactive (see col. 2, lines 39-44). Lamination of a matrix having pore sizes of less than 50 μm , while the next layer may have pore diameters of greater than 100 μm . Note that bilayer matrices are specifically recited for preventing tissue ingrowth for some period of time. One of the properties described by Shasti et al in selecting the appropriate polymers for the composite is the time required for each to degrade (see col. 13, lines 28-37). Another is porosity as described at col. 2, lines 28-30. Preferred porosity is at least 20% , but may be greater than 95%. Preferred materials for the laminated composites include various synthetic polymers listed at col. 3, lines 42-52, and include polylactic acid, collagen and gelatin. The instant claims are anticipated by Shastri et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shastri et al, and further in view of Levene et al.

Shastri et al disclose a composite polymer matrix which is porous (see Abstract; column 2, lines 28-43.) The voids in the matrix may range from connected, to partially connected, to not connected at all (see col. 1, lines 58-65). Bioactive agents may be incorporated into this matrix (see col. 2, lines 39-40). The matrix may further include bioerodible fibers (see col. 2, lines 57-60). Multilayer matrices are specifically recited at col. 25, lines 40 et seq. And a specific suggestion to combine two materials with different properties, and pore sizes is found at col. 26, lines 1-11. This matrix may also contain a bioactive (see col. 2, lines 39-44). Lamination of a matrix having pore sizes of less than 50 μm , while the next layer may have pore diameters of greater than 100 μm . Note that bilayer matrices are specifically recited for preventing tissue ingrowth for some period of time. One of the properties described by Shastri et al in selecting the appropriate polymers for the composite is the time required for each to degrade (see col. 13, lines 28-37). Another is porosity as described at col. 2, lines 28-30. Preferred porosity is at least 20%, but may be greater than 95%. Preferred materials for the laminated composites include various synthetic polymers listed at col. 3, lines 42-52, and include polylactic acid, collagen and gelatin. The reference differs only in the specific recitation that one of the layers have a higher biodegradation rate, porosity, pore size, bioactive content or other characteristic.

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However, Shastri et al does include the broad teaching that the two layers be selected for their different properties (as cited above). This would appear to encompass applicant's use of the word "incompatible". Further, since Shastri et al specifically recite characteristics for selection of polymer components including biodegradation rate, porosity and pore size, it would be well within the skill of the ordinary practitioner to select one of these characteristics in order to obtain the desired therapeutic results from the scaffold. Indeed, Shastri et al speaks specifically to this point at col. 20, lines 58-67. Further, lamination of crosslinked layers with noncrosslinked layers is specifically recited at col. 25, lines 58-67. As such, it would have been well within the skill of the ordinary practitioner to use layers with different biodegradation rates, porosity, or pore size in order to obtain the therapeutic results required in healing various types of tissues. The porous medical device with with one layer having bigger pore sizes, porosity, or biodegradation rate than the other, and containing a biodegradable fiber, and bioactive, would have been obvious given the teachings of Shastri et al.

Levine et al, Athanasiou et al, and Vyakaram et al are cited as patents of interest in their disclosures of porous polymer scaffolds for use in tissue engineering.

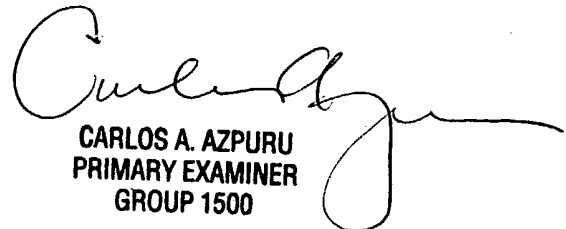
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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